

## MODULE SIX: SPECIAL ISSUES

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### ABSTRACT

*The objective of this module is to cover ground that was not covered in-depth in any of the other modules, including: scientific misconduct, issues concerning the publication and ownership of research results (authorship guidelines – who is eligible to be considered an author, or contributor to a scientific paper etc.), special problems occurring in social science and epidemiological research, and the problems pertaining to conflicts of interest the various players in biomedical research activities could encounter.*

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### SCIENTIFIC MISCONDUCT

*What is scientific misconduct?*

A widely accepted definition of research misconduct, as it appears in the USA Federal Policy on Research Misconduct, is as follows:

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or honest difference of opinion.<sup>1</sup>

<sup>1</sup> Available at: [http://www.ostp.gov/html/001207\\_3.htm](http://www.ostp.gov/html/001207_3.htm)

Other practices falling outside the realm of those commonly accepted by the scientific community also constitute scientific misconduct. They include, but are not limited to, the following:

- Deviation from or failure to adhere to the proposed protocol without proper permission
- Misrepresentation
- Falsification of credentials
- Deception in the research proposal
- Deception in the carrying out of research
- Piracy of materials
- Failure of informed consent
- Breaches of confidentiality
- Undertaking research without clearance from a research ethics committee
- Any one of all other deviations from accepted ethical standards.

The *Declaration of Helsinki*, developed by the World Medical Association,<sup>2</sup> provides ethical guidelines to be followed by medical researchers in their dealings with human participants. Many instances of medical misconduct can be studied based on deviation from the Declaration.

#### *Examples of scientific misconduct*

As a reference, we shall consider some famous and flagrant accounts of scientific misconduct. Imagine in each instance that you are a member of a research ethics committee. Your committee has to evaluate where the research went wrong.

The Tuskegee study, begun in 1932, aimed to determine by autopsy what syphilis does to the human body. Participants in the study, poor, black men in Macomb, Alabama, were neither told that they had syphilis nor were they treated for it. While at the start of the study there was no known cure for syphilis, 15 years into it penicillin was found to be the proper treatment for the disease. Still, the Tuskegee participants were never given penicillin, and the study ran for more than four decades.

So, how many instances of medical misconduct can you think of in this short introduction?

Just through an examination of the *Declaration of Helsinki*, we can find some instances of misconduct committed by the Tuskegee scientists. First, special consideration must be made for the economically and medically disadvantaged. But this study gave

<sup>2</sup> World Medical Association. 2000. *Declaration of Helsinki*.

no such consideration to their population. Rather, it seems the researchers chose that population specifically for the reason that they were so disadvantaged. The men on whom they conducted the research were poor, and had little hope of more suitable medical attention. Not only that, but there was a blatant disregard for informed consent. The patients were never told that they were participants in a trial. They never volunteered to forego standard treatment for syphilis. In fact, the men were not even told that they had syphilis; only that they were being treated for 'bad blood.'

The behaviour of the researchers 15 years after the start of the study constitutes further misconduct. A cure for syphilis was found and withheld from participants. There is no ethical justification for these actions. Not only were the men denied the knowledge of their affliction, but they were also denied available treatment for it. They were never made aware of the disease they had, and never told that they were part of a research study.

South Africa's recent history provides us with another instance of scientific misconduct. The head of clinical oncology and haematology at the University of the Witwatersrand, Professor Werner Bezwoda, presented a paper in May of 1999 to the American Society of Clinical Oncology (ASCO) and then presented that same paper at the European Cancer Conference later that year. The paper was titled 'Randomized Controlled Trial of High Dose Chemotherapy (HDC) Versus Standard Dose Chemotherapy for High Risk Surgically Treated Primary Breast Cancer.'<sup>3</sup> Though numerous randomised clinical trials on HDC showed no considerable benefits of the expensive treatment, Bezwoda maintained, based on his research results, that HDC was significantly beneficial.

Bezwoda was the only researcher to have found beneficial effects of such aggressive therapy. Obviously, this created a fair amount of excitement, and ASCO began planning a large study in an attempt to duplicate his results. In early 2000, ASCO sent a delegation to South Africa to try and understand what he had done in order to plan a large definitive study involving the major oncology groups in Europe and the United States. Bezwoda provided that delegation with clinical files of only about one third of the supposed number of trial participants and none of the control

<sup>3</sup> W.R. Bezwoda, L. Seymour & R.D. Dansey. High Dose Chemotherapy with Hemopoietic Rescue as Primary Treatment for Metastatic Breast Cancer: A Randomized Trial. *Journal of Clinical Oncology* 1995; 13: 2483–2489. Retracted in the *Journal of Clinical Oncology* 2001; 19: 2973.

group. This was the first sign that something was not right. A member of the ASCO delegation informed the chairman of the university's research ethics committee of their concern. A review of Bezwoda's applications to the research ethics committee was immediately set up but before this began Bezwoda provided a signed admission that he had misrepresented his research results at the ASCO congress; the control group in his study had not received the treatment combination that he reported but a different one.

The University of the Witwatersrand acted quickly; there was a formal disciplinary hearing within weeks. Professor Peter Cleaton-Jones, the chairman of the research ethics committee for that university as well as the Assistant Dean for Research in the Faculty of Health Sciences, and the complainant in the case, questioned Professor Bezwoda. Cleaton-Jones:

He confirmed his misrepresentation of results at the ASCO congress and admitted that the form that he had provided for the ASCO delegation that was purported to have come from the Pharmacy and Therapeutics Committee of the Johannesburg Hospital allowing him to do his study was in fact false and had been forged by him. The reasons for spotting that were quite simple; the letter head that was used was out of kilter with the time, there was no meeting on the date that was listed, one person who was listed as an assessor was not on the university staff . . . At the same time, I also presented evidence that there had never been an application to the ethics committee by him for the study that he reported at the congress.

Eventually, Bezwoda admitted that he never did a randomised controlled trial, but that he had done a retrospective look at his patients' files which he presented as if it was a randomised controlled trial, which is the 'gold' standard in clinical research.

So what, exactly, were Bezwoda's breaches of research conduct? According to Cleaton-Jones they are as follows:

The university requires that any studies on humans must be approved by a research ethics committee of the university. The second thing is that any clinical trial that is going to be done in an academic hospital at the time, had to go through a separate pharmacy and therapeutics committee within the relevant hospital. And what would normally happen is an applicant wishing to do a clinical trial would either put in two applications in tandem, or in sequence, one to the hospital's committee and one to the university's committee, and have them both

considered . . . It was a two stage procedure . . . He never got consent from the hospital, nor from the university. Then he presented a paper in which he'd said he'd given one form of treatment when he'd actually given another. He also said it was a randomised clinical trial, which is the highest level of clinical trial, but at his disciplinary hearing he admitted was not done, it was a retrospective evaluation of patient treatment. The next thing that he did was to provide a false certificate, or false clearance, from the pharmacy and therapeutics committee to the interviewing committee . . . plus he gave no control patient files at any stage to the ASCO delegation.

In other words, investigators had found that Bezwoda was guilty of, among other things, the following breaches: he had bypassed the university's research ethics committee, he had no record of patients' informed consent forms, he potentially fabricated data, misrepresented the race of his participants, and lied about treatments that were used.<sup>4</sup>

The danger in all this was that he told a large number of specialist colleagues at an oncology congress that a particular combination of treatments would work. Clinicians attending his talks might then be convinced of the merits of such treatment, and use it on their patients. Such treatment, it should be noted, is both expensive and debilitating. Potentially, people would suffer from aggressive therapy that might not work. Those who had read, believed, and relied on the results of Bezwoda's 'research' had spent large amounts of money on harsh, painful therapy that, in the end, was not advantageous. Furthermore, US researchers might well have spent huge resources in an effort to reproduce the oncologist's results instead of using those researchers in more promising research activities.<sup>5</sup> The university's disciplinary hearing found Bezwoda guilty of bringing the university into disrepute and contravening university rules and regulations thereby; he was summarily dismissed from the university staff.

<sup>4</sup> J. Sprague Jones. Disappointment and Deceit in High-Dose Chemotherapy Trials. *Breast Cancer Action Newsletter* 2000; 59. Available at: <http://www.bcaction.org/Pages/SearchablePages/2000Newsletters/Newsletter059A.html>

<sup>5</sup> R.B. Weiss, R.M. Rifkin, F.M. Stewart, R.L. Theriault, L.A. Williams, A.A. Herman & R.A. Beveridge. High-dose Chemotherapy for High-Risk Primary Breast Cancer; an On-Site Review of the Bezwoda Study. *Lancet* 2000; 355: 999–103. P. Cleaton-Jones. Scientific Misconduct in a Breast Cancer Chemotherapy Trial: Response of the University of the Witwatersrand. *Lancet* 2000; 355: 1011–1012.

Subsequently in 2003, Bezwoda was found guilty of improper conduct of a disgraceful nature by the Medical and Dental Professional Board of the Health Professions Council of South Africa, and suspended from clinical practice for a period.

*What are the ramifications of misconduct?*

The possible effects of such misconduct can be disastrous. In the case of Bezwoda, he instilled in many patients a false hope of treatment and alleviation of breast cancer that would not come about, or at least would not come about any stronger or faster than if the patients had used other, less expensive, and less debilitating forms of treatment. But the implications of fraudulent data can run further than effects on the immediate patients involved, dire though those consequences certainly may be. Consider the money and time spent and the resources lost by researchers trying to replicate data that never existed in the first place.

There is yet another issue that one has to consider once instances of medical misconduct surface. The previous work of the author or researcher in question must be doubted and scrutinised. In short, all the past work of a guilty scientist must be called into question. This happened with Bezwoda as well. A subsequent enquiry into an earlier publication of his resulted in the article being retracted by the journal in which it had been published and the tainting of the reputation of his co-authors.<sup>6</sup>

In a useful book called *Fraud and Misconduct in Medical Research*, some of the telltale signs of such misconduct are discussed. They include data that shows very large differences between experimental groups when similar research groups got very different data, when data cannot be reproduced, when values in tables and graphs do not correlate with printed data or do not 'add up' across tables, when there are different amounts of observational points in graphs than in written data, when significant data arises from small study groups when most investigators needed larger ones, etc.<sup>7</sup>

<sup>6</sup> R.B. Weiss, G.G. Gill & C.A. Hudis. An On-Site Audit of South African Trial of High Dose Chemotherapy for Metastatic Breast Cancer and Associated Publications. *Journal of Clinical Oncology* 2001; 19: 2771–2779.

<sup>7</sup> S. Evans. 1993. Statistical Aspects of the Detection of Fraud. In *Fraud and Misconduct in Medical Research*. S. Lock & F. Wells, eds. London. BMJ Publishing Group: 61–74.

## CONFLICT OF INTEREST

*What is a conflict of interest?*

Conflict of interest arises when a participant in the research process, at any level – researcher, author, editor, peer-reviewer, etc. – has ties to organisations or interests that could undermine the integrity of the work or their judgement while conducting that work. Such bias can arise for a number of reasons, ranging from personal relationships, to the desire and pressure to publish speedily, to, most grossly, those conflicts that arise due to a financial relationship with the industry about which the research is being conducted. Frequently, for instance, researchers are not permitted to publish negative results in order to ensure that a trial failure does not have too negative an impact on a pharmaceutical company's share price. *Vice versa* there have been pressures in the past to put a spin on trial results that could assist a given company's market value.

Unfortunately, though such conflicts can certainly be an ethical hindrance to medical research, even constituting misconduct in some cases, such practice is commonplace. While Arthur Caplan, the director of the University of Pennsylvania Centre for Bioethics, is an outspoken opponent of conflict of interest, the bioethics centre of which he is the head is supported by pharmaceutical companies. But 'by no means does Caplan's centre stand alone in its coziness with industry. The University of Toronto houses the Sun Life Chair in Bioethics; the Stanford University Centre for Biomedical Ethics has a program in genetics funded by . . . a gift from SmithKline Beecham Corporation; the Merck Company Foundation has financed a string of international ethics centres in cities from Ankara, Turkey to Pretoria, South Africa . . .'

<sup>8</sup>

*Various kinds of conflicts of interest and disclosure*

The International Council of Medical Journal Editors addresses the concern of conflict of interest. They put the onus of identifying and admitting to potential conflict of interest on the parties involved. For instance, authors of a research paper are responsible for disclosing potential factors that could bias their work. If the research is sponsored by an industry or organisation with

<sup>8</sup> C. Elliott. Pharma Buys a Conscience. *The American Prospect* 2001; 12. Available at: <http://www.prospect.org/print/V12/17/elliott-c.html>

vested interest in the results of the work, the author must specify as such.<sup>9</sup>

But it is not only authors who are potentially affected by conflicts of interest. If an external reviewer of the research paper has some bias on a certain subject, it is his duty to make editors aware of any conflicts of interest. If the bias is strong enough, that reviewer should disqualify himself from reviewing the specific paper. If the reviewer does not disqualify himself, but the editor deems that there remains a conflict that will bias the review, the editor can and should disqualify that reviewer.

Some forms of writing carry with them stronger bias due to conflict of interest. The *New England Journal of Medicine*, for instance, has more stringent requirements governing conflicts of interest for certain articles than for others. 'Our conflict-of-interest policy for editorialists, established in 1990, is stricter than that for authors of original research papers. Since editorialists do not provide data, but instead selectively review the literature and offer their judgments, we require that they have no important financial ties to companies that make products related to the issues they discuss. We do not believe that disclosure is enough to deal with the problem of possible bias.'<sup>10</sup>

The best practice to ensure the integrity of the research process is for authors, reviewers, editors, and anyone else, to avoid ties that limit their control, whether by restricting publication or by limiting the scope of the research. Other than that, the only acceptable practice is complete disclosure. In an appendix to the *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2000), the South African Department of Health insists on limiting conflicts of interest. Their guidelines, shown below, are to be followed when conducting scientific research in the country.

1. A member of the Board or of the staff or of any committee of the Authority, may not vote at, attend or in any other manner participate in the proceedings of any meeting or hearing of the Board or any committee of the Authority if:
  1. In relation to an application for the registration of a medicine, complementary medicine, veterinary medicine,

<sup>9</sup> International Committee of Medical Journal Editors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*. Available at: <http://www.icmje.org/index.html>

<sup>10</sup> M. Angell. Is Academic Medicine for Sale? *The New England Journal of Medicine* 2000; 342. Available at: <http://content.nejm.org/cgi/content/full/342/20/1516>

- clinical trial or device, that member or that member's immediate family member or business partner is a director, member or business partner of or has an interest in the business of the applicant of any person who made representations in relation to the application; **or**
2. In relation to any matter before the Authority, has any interest that precludes or may be perceived as to preclude that member from performing that member's functions as a member of the Authority in fair, unbiased and proper manner.
  2. For the purpose of this section, 'interest' includes, but is not limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind.
  3. If at any stage during the course of any proceedings of the Board or committee of the Authority has an interest contemplated in subsection (1), that member:
    1. must forthwith and fully-disclose the nature of that member's interest and leave the meeting or hearing in question so as to enable the remaining members of the Board or any committee of the Authority to discuss the matter and determine whether that member should be precluded from participating in such proceedings by reason of a conflict of interests, *and*
    2. such disclosure and the decision taken by the remaining members of the Board or any committee of the Authority regarding such determination, must be recorded in the minutes of the proceedings in question.<sup>11</sup>

It is also integral that any participants in the research be made aware of possible conflicts of interest. They should be told if the research is being conducted with motives other than for their own well-being or the well-being of others.

## SOCIAL SCIENCE AND EPIDEMIOLOGICAL RESEARCH

### *Ethical considerations for epidemiological research*

The advent of the HIV/AIDS epidemic has accentuated the need for epidemiological research ethics guidelines since, in efforts to

<sup>11</sup> South African Department of Health. 2000. *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa*. Appendix E. Available at: [http://196.36.153.56/doh/docs/policy/trials/trials\\_contents.html](http://196.36.153.56/doh/docs/policy/trials/trials_contents.html)

understand the efficacy of certain treatments, it is important to track the rate of spread of the disease. But along with this sort of research occurred certain ethical problems. On the one hand, the results of such studies can prove beneficial and can greatly assist in calculating prevention and treatment plans. On the other hand, such benefits can often come at the expense of the study's participants. In a world of intense stigmatisation, such information can be harmful to research participants.

There are numerous ethical considerations that need to be taken into account in epidemiological research of any kind. They include informed consent, maximising benefit, minimising harm, respecting confidentiality, and issues to do (again) with conflicts of interest.<sup>12</sup> Before any epidemiological study should be undertaken, these factors should be substantially considered.

Furthermore, most social science research tends to be demanding on the participants. Such research is frequently disruptive and intrusive. The international consensus view today is that it would not be ethical for a researcher to utilise a local community and not contribute either to the individual or the community at large. No immediate good comes to the participants or the community by the researcher's intrusion (even though the results of her research may prove fruitful later, but that has yet to be determined), so the researcher, depending on her capabilities, should contribute in some way to the benefit of the community. For instance, a social science researcher enters a community to gather HIV/AIDS information. That researcher is likely well versed on the subject, and could volunteer to tutor in area schools or adult education programmes.

Another central ethical issue has to do with partners of participants in epidemiological research. Say you would like to study the development of HIV prevalence among HIV sero-discordant couples. Is it ethically acceptable not to inform the HIV-negative partners of HIV infected participants of this fact in order to allow them to protect themselves? However, if you did so, your study would be of little value, because by virtue of you informing the sexual partner(s) of HIV-positive participants, you would change the normal course of the epidemic among such couples in a way that would not normally have occurred in the 'real world.' There has been a lot of international discussion on this matter. Most

<sup>12</sup> The Council for International Organizations of Medical Sciences (CIOMS). 1991. *International Guidelines for Ethical Review of Epidemiological Studies*. Geneva. Available at: [http://www.cioms.ch/frame\\_1991\\_texts\\_of\\_guidelines.htm](http://www.cioms.ch/frame_1991_texts_of_guidelines.htm)

people concluded that you would have an obligation to inform the HIV-negative partners of infected participants in such a study, because by virtue of your knowledge of their sero-discordance you would no longer be an 'innocent bystander' and to some degree could be held (partially) responsible for infections that occur because you have not informed the uninfected party.

There is a further problem often discussed in the research ethics literature and also in many guidelines. We will touch upon it only briefly, because it is, thankfully, not a major concern in South Africa. However, in some societies women will find themselves in circumstances whereby their participation depends on their husband's assent. This frequently applies to Islamic societies. There is lively discussion among Islamic bioethicists and religious scholars about whether this procedure is actually in line with the religion's prescriptions. For our purposes, the answer to this question is not important, because practically this *is* what often happens. International research ethics guidelines such as those issued by CIOMS propose the following *modus operandi*: ask the husband for approval and proceed to approach the wife for her first person voluntary informed consent only after he has agreed that his wife may participate. Importantly, do not allow his assent to become a substitute for his wife's consent. Ensure that you develop a mechanism whereby the husband would not be aware if the wife actually declined to participate in your research, while her husband is in favour of it.

The American College of Epidemiology has published widely recognised ethics guidelines that you should consider familiarising yourself with.<sup>13</sup> It is clear from these guidelines that the researcher should be cognisant of the necessity of repaying the community in which she works. This ethical consensus view requires a balance between the benefits to the whole community and the risks to the individuals who are part of the population study.

### *The special case of HIV/AIDS*

Since the kind of epidemiological research generally done in South Africa is very specific in its nature, namely concentrating on HIV/AIDS, specific epidemiological guidelines for just that purpose are necessary. The South African Department of Health

<sup>13</sup> American College of Epidemiology. January 2000. *American College of Epidemiology Ethics Guidelines*. Available at: <http://www.acepidemiology.org/policystmts/EthicsGuide.htm>

noted as much in its *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* 2000. According to that document, new considerations come into view, including 'access to clinical trials, informed consent, use of medications after the completion of drug trials, drug toxicities, informed consent, long term side effects, the appropriateness of proposed research for South Africa, and the release and publication of the research results.'<sup>14</sup>

Take this into consideration. In many drug trials, HIV-positive participants rely on the medication as their only affordable means of treatment. What happens to them when the trial is over? Participants must be made aware of the implications of taking a drug only for the duration of the research. Furthermore, a truly ethical study will include considerations pertaining to the post-trial availability of the treatment regimes under consideration in a trial. It does not seem ethical to withdraw treatment, should the treatment prove beneficial, from study participants who have no means of continuing their treatment.

Ethics committees must consider the benefit, not only to the individual, but also to the community as a whole. Is the medicine so expensive that the research participants, and other members of their community for that matter, will not have the resources to use that medication? If this is the case, an ethics committee will have to seriously consider whether or not such a trial is ethical.

An important part of epidemiological research in South Africa deals with the HIV prevalence. While it is beneficial to many individuals to have knowledge of their HIV status, there are also frequently negative consequences. Personal and social stress, societal rejection, and stigmatisation are just some of the known adverse outcomes of an HIV positive result.

Thus, first and foremost, testing must be confidential. While the participants who are found to be HIV-positive are counselled to disclose such results to sexual partners, and other parties at risk of serious bodily harm, ultimately that is not for the researcher to decide and/or to disclose to such parties. Furthermore, such studies should provide for research participants', in the words of the South African Department of Health:

1. Adequate pre-test counselling;
2. Informed consent. In the case of children informed consent must be obtained from the parent or lawful guardian, as well

<sup>14</sup> South African Department of Health. 2000. *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa*. Chapter 9.

as from the child if she is sufficiently mature. Consent for HIV testing should form a part of the consent document for research that requires the HIV testing of an individual;

3. Adequate post-testing counselling; *and*
4. Referral to an accessible centre for ongoing psychosocial support and basic medical care. The centre should provide care that conforms at least to the national standard of care for HIV prevention and treatment including the provision of condoms.<sup>15</sup>

In population-based studies on HIV transmission prevention, the Department of Health stipulates not only that the community as a whole consent, but the individual participants must consent as well. Furthermore, here we revisit a topic covered earlier in this module. It is the ethical duty of a researcher to confer all valid methods of prevention and treatment to the research participants.

## PLAGIARISM

*What is plagiarism?*

The theft of intellectual property, or, in other words, to pass off another's ideas, data, or other elements of research as one's own, constitutes plagiarism. This stricture applies to all areas of research, be it simply an introductory section full of background information or hard data. If you 'lift' another's words without the proper citation, you have committed plagiarism. If you introduce a unique idea or theory without citing its creator, you have committed plagiarism. If you paraphrase liberally from another's work or use the exact examples or organisation from someone else's paper without citing that source, you have committed plagiarism.

There are both moral and legal implications involved in plagiarism, and as it is another form of research misconduct, it can merit harsh consequences.

Morally, it should be clear that one should not steal the work of another. The proper source, author, or innovator must be credited; they deserve it.

Instances of plagiarism can have dire consequences for the guilty student or researcher. As a student, repercussions run a massive gamut. One may receive only a warning, or receive 0% credit for a particular assignment, or in certain cases, a student

<sup>15</sup> South African Department of Health. 2000. *Guidelines for Good Practice in the conduct of Clinical Trials in Human Participants in South Africa.*

can be expelled from his or her institution. Plagiarism in the professional world can be career threatening. Once a plagiariser has been identified, it is likely that this reputation will follow her indefinitely, and her work will never again be trusted.

## AUTHORSHIP AND PUBLICATION ISSUES

*What are the criteria for authorship?*

All those who contribute to a research project must be credited appropriately. But there certainly is a grey area, and authorship guidelines must be followed in order to assure that all parties involved are properly recognised for their contribution(s).

In order to discuss these and other matters regarding the format of manuscripts submitted to journals, the editors of a number of medical journals met in Vancouver, British Columbia in 1978. What was then dubbed the Vancouver group has expanded to become the International Committee of Medical Journal Editors (ICMJE). It is by these guidelines that the vast majority of medical journals abide, and so we will discuss authorship related issues based on this pivotal document.

Imagine a large research group. Everyone has his or her function. Everyone is working towards the completion of the research and the eventual publication of the report. But who in this group deserves to be an author, and who should be mentioned in the 'Acknowledgement' sections?

The ICMJE states in its guidelines that 'all persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.'<sup>16</sup>

So what exactly are the criteria for authorship? According to the ICMJE, there are three necessary condition one must meet in order to claim (co-)authorship:

1. 'Substantial contributions to conception and design, or acquisition of data, or the analysis and interpretations of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be published.'<sup>17</sup>

<sup>16</sup> International Committee of Medical Journal Editors, *op. cit.* note 9.

<sup>17</sup> *Ibid.*

Those, and only those who meet all three of the above stipulations, can be named authors, while those who meet only some of the requirements or otherwise facilitate the research by contributing to funding, data collection, editorial work, etc. should be named in the 'Acknowledgements' section.

*What are the relevant publication issues?*

According to the Medical Research Council of South Africa, not only are scientists entitled to be credited for their research, but they also have 'a moral obligation to share their findings with other investigators, clinicians and society, for the mutual benefit of all.'<sup>18</sup>

That being said, researchers must still adhere to ethical principles during publication. Starting with the obvious, ethical practice must be followed throughout the research process in order for the paper to qualify for publication. The original protocol must have been approved by a properly constituted ethics committee *before* the start of research. The collection of data must have adhered to ethical guidelines, and all components of the compilation of the paper must have otherwise held fast to the various other aspects of research ethics described in this course.

The ICMJE pinpoints other concerns in publication that must be addressed. If the majority of a manuscript submitted for publication can be found in another published article, or in its entirety in another journal, this constitutes redundant publishing and should thus be avoided. 'Readers of primary source periodicals deserve to be able to trust that what they are reading is original unless there is a clear statement that the article is being republished by the choice of the author and editor. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources.'<sup>19</sup>

Since clearly most journals would not wish to commit 'redundant publishing', the author should make clear to the editor of that journal all previous publications of similar or identical work. To knowingly fail to do this would constitute misconduct.

Premature publication must also be avoided. Researchers are under immense pressure to publish, and to do so quickly, but what happens sometimes is that research is published long before it

<sup>18</sup> Medical Research Council of South Africa. 2002. *Guidelines on Ethics for Medical Research: General Principles*. Available at: <http://www.mrc.ac.za/ethics/ethics.htm>

<sup>19</sup> International Committee of Medical Journal Editors, *op. cit.* note 9.

should be. The data collection can be sloppy, the writing may suffer, and the paper as a whole can be shoddy due to pressure to publish quickly. This can compromise the integrity of the work.

## CONCLUSION

Researchers must adhere to the various ethical guidelines discussed in this and other modules to ensure the dignity and rights of human participants are upheld in research. The various issues in research ethics described in this module all require careful scrutiny of the research process by regulatory agencies but also serious self-reflection on the part of the researcher him- or herself. It is certainly true that advances in technology and medicine follow fruitful research, leading eventually to an improvement of the human condition. But such advancements should not come at the cost of the integrity of the scientific community, or the dignity and well-being of research participants.

## CASE STUDIES

### *Case study I*

A researcher submits a protocol to your ethical review board. He is proposing to enter a community in rural South Africa and live there for six weeks conducting interviews on patients entering a medical clinic there. He will test the blood of each subject for HIV in order to write a paper to be submitted to a medical journal in England about the spread of HIV in South Africa and the use and relative success of various treatments. At the end of the six weeks, he will compile his data and write a report about the prevalence of HIV on that community and which treatments seem to be most popular and/or most effective.

*Would you approve this project? Why or why not?*

### Model Answer

As it stands, this project would not be approved. In no part of the proposal does the researcher propose any benefit to the community. It would not be ethical for him to enter the community, use time and resources from his research participants, but in no way help the community. Before the research ethics committee can approve the proposal, the researcher must propose adequate benefits that he intends to provide while conducting the research or after the research has concluded.

*Case study II*

While attending a lecture on Disease X, a light bulb goes on in your head, and you think that a steady dose of Drug V could cure the symptoms. After a bit of reading and research, you find that no one has tried Drug V before and you recruit a team of researchers, as well as find a willing sponsor, to test your hypothesis. Sure enough, patients treated with Drug V show a decrease in the purple polka dots associated with Disease X. While you are a decent writer, you do not want to take the brunt of this challenge alone and some of your fellow researchers do the majority of the writing, though you certainly have your share of input. Once a rough draft has been written, primarily by two of your colleagues but with your help, the three of you edit and revise the paper and submit it for publication to a renowned medical journal.

Should You be Listed as an Author? If So, Who Else is an Author? If Not, Who is an Author?

You are clearly an author. You have met each requirement set forth by the ICMJE. 1) You were certainly part of the conception and design of the experiment and you participated in acquisition of data. 2) While you were not the main writer of the draft, you contributed and revised it for intellectual content. 3) As an editor, you approved the final version of the paper. So, without a doubt, you are an author.

As far as other authors, the two researchers who helped write the rough draft as well as revise the final version are to be authors as well. They also acquired data, drafted the original article, and approved the final paper. It is up to the three of you to decide on the order in which your names will appear when you submit your paper for publication.

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